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10/523,076	01/25/2005	Hiroyuki Tokunaga	2005_0071A	8391

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EXAMINER	
OLSEN, KAJ K	

ART UNIT	PAPER NUMBER
1795	

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07/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/523,076	TOKUNAGA ET AL.	
	Examiner	Art Unit	
	KAJ K. OLSEN	1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *18* is/are allowed.

6)☒ Claim(s) *2-7,9-11 and 13-17* is/are rejected.

7)☒ Claim(s) *8,12 and 19-23* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6-12-2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The outstanding objection to the specification has been withdrawn in view of the amendment.

Information Disclosure Statement

2. The citation on the information disclosure statement of 6/12/2008 has been lined through because the examiner already cited this reference and its inclusion here was redundant.

Claim Rejections - 35 USC § 112

3. The outstanding 112 rejection to the claims have been withdrawn in view of the amendment to the claims.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 2-5 and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Nankai et al (USP 5,120,420).

6. With respect to claims 2 and 5, Nankai discloses a standard solution that includes absorbic acid (col. 9, ll. 31-54), which the applicant evidences is a reducing substance (see claim

5). With respect to limitations drawn to the measuring apparatus itself and how the sample solution is to be utilized, that is only the intended use of the apparatus and the intended use need not be given further due consideration in determining patentability.

7. With respect to claims 3 and 14 (those limitations not covered above), because the ascorbic acid of Nankai is one of the same reducing substances utilized by the instant invention, it inherently would provide a larger value of oxidation current during any first potential in comparison with a second potential. With respect to actually applying any first or second potentials, how the unclaimed measurement apparatus is to be utilized does not further define the actually claimed standard solution.

8. With respect to claims 4, 13, and 15 (those limitations not covered above), Nankai evidences that ascorbic acid provides an oxidation current with 0.6 V. See col. 10, ll. 21-29.

9. Claims 2-4 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Ye (USP 5,723,284).

10. Ye discloses a control solution (i.e. standard solution) containing a mediator, such as ferricyanide, which at least partially exists as the reducing substance ferrocyanide. See col. 5, l. 45 through col. 6, l. 52. Hence, the portion of the control solution that exists as the reduced ferrocyanide would read on the defined reducing substance of the claims. Moreover, fig. 1 evidences that a component in the control solution is undergoing oxidation (i.e. a reducing substance) because the control solution is providing a positive oxidation current during the burn period. This is presumably the residual reduced form of the mediator present in the control solution. With respect to the details of the measurement apparatus or how the measurement apparatus is to be utilized, as discussed above for Nankai, that is only the intended use of the

standard solution and the intended use need not be given further due consideration in determining patentability. With respect to actually applying any first or second potentials, how the unclaimed measurement apparatus is to be utilized does not further define the actually claimed standard solution. However, see the 103 rejections below.

11. With respect to the reducing substance being oxidized at the set forth potentials, the burn voltage of Ye utilized for generating the oxidized current is 0.4 V (col. 7, ll. 44-55) evidencing that the reduced form of the mediator (i.e. reducing substance) is oxidized within the claimed range.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 6, 7, 9, 11, 16, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ye in view of WO 02/44705 (hereafter "WO '705"). For the discussion of WO '705, the examiner will be relying on the English language disclosure of Miyazaki et al (USP 7,232,510). All cited text for WO '705 refers to the text from Miyazaki.

14. With respect to claim 6, Ye discloses a method for determining a substance (glucose) contained in a sample solution (whole blood) on the basis of an oxidation current value which is obtained by applying a first potential by a driving power supply (i.e. the burn potential) to an electrode portion of a biosensor having a working electrode and a counter electrode (i.e.

reference electrode), a reagent layer reacting with the sample solution supplied to the electrode portion for a first time period (i.e. the burn period), then stopping the application for a given time period (i.e. the wait period), and applying a second potential for second time period (i.e. the read period). See fig. 1, col. 4, ll. 15-28 and col. 7, l. 44 through col. 8, l. 3. As discussed above in the 102 rejection, Ye further discloses the use of a standard solution (i.e. control solution) containing a reducing substance (i.e. the reduced form of the mediator) for controlling the precision of the measurement and the sample and control solutions are discriminated from each other on the basis of the oxidation current value obtained by applying the first potential and the oxidation current value obtained by applying the second potential. In particular, Ye notes that the control substance has a higher read to burn (R/B) ratio and the discrimination relies on the observance of a higher R/B ratio. See col. 6, ll. 38-47. Ye did not explicitly disclose that the second potential is smaller than the first potential. WO '705 discloses the use of a burn voltage V1 that exceeds the read voltage V2 and indicates that this choice of higher V1 with subsequently lower V2 was motivated by the desired balance between reaction product consumption and reaction speed during the burn period with the desire to apply a V2 only high enough to oxidize the ferrocyanide. See fig. 9 and col. 14, l. 65 through col. 15, l. 39. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of WO '705 and utilize a read voltage that is smaller than the burn voltage for the method of Ye in order to provide voltage levels that better balance the different goals of the burn and read periods.

15. With respect to claim 7, the oxidation current during the first potential is "definitely different" from that of the sample whereas during the read period they are "similar", giving the claim language its broadest reasonable interpretation. See fig. 1 of Ye.

16. With respect to claim 9, see Ye, col. 6, ll. 21-47.

17. With respect to claim 11, the burn voltage of Ye utilized for generating the oxidized current is 0.4 V (col. 7, ll. 44-55) evidencing that the reduced form of the mediator (i.e. reducing substance) is oxidized within the claimed range.

18. With respect to new claims 16 and 17, see the rejection of claims 3 and 4 over Ye and the rejection of claim 6 over Ye and WO '705 above.

19. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ye in view of WO '705 as applied to claim 6 above, and further in view of EP 1 156 324 (hereafter "EP '324").

20. The references set forth all the limitations of the claim, but did not explicitly disclose the use of the set forth discrimination function. EP '324 discloses in an alternate method for differentiating standard solutions from sample solutions and teaches the use of a discrimination function employing a discrimination parameter as an independent variable whereby a value is input into the discrimination function to be taken as a discrimination index. See paragraphs 0027-0057. Because a discrimination index provides a convenient computation means for deciphering whether a given measurement is sample or standard, it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize known computational means as disclosed by EP '324 to analyze the method of Ye and WO '705 to yield the predictable result of having the sample measurement differentiated from the standard measurements.

Allowable Subject Matter

21. Claims 8, 12, and 19-23 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

22. Claim 18 is allowed.

23. The following is a statement of reasons for the indication of allowable subject matter: With respect to claims 8 and 12, see the previous office action for indication of allowable subject matter. With respect to claim 18, this claim appears to set forth the method of claim 6 with the solution of claim 5. Because does not disclose nor render obvious the use of the reducing substances of claim 5 (see objected to claim 12), claim 18 is thereby allowable. With respect to claims 19-23, these claims also contain allowable subject matter for the same reason that claim 12 did.

Response to Arguments

24. Applicant's arguments filed April 30th, 2008 have been fully considered but they are not persuasive. With respect to the rejection relying on Nankai, applicant urges that glucose standard solution discussed by Nankai in col. 9, ll. 31-54 cannot be used as a solution to control a precision of a measurement apparatus. Whatever the merits of this assertion are, how the standard solution of the claimed invention is to be utilized does not further define the actual standard solution. Amended claim 2 is drawn to a standard solution having a reducing substance and a predetermined amount of substrate. Nankai discloses those features in its glucose standard

solution and thereby reads on the defined solution of the claims. The remainder of claim 2 is drawn to the intended use of this standard solution and the intended use need not be given further due consideration in determining patentability. For example, claim 2 further defines the standard solution as "which is used when determining a substrate contained in a sample solution by using a measurement apparatus having...." This is all clearly drawn to how the standard solution is to be utilized and doesn't further define the solution itself. Similarly, the actual choice of first and second potentials utilized with the standard solution only further define the use of the measuring apparatus, which is not part of the claimed invention anyway.

25. With respect to the 102 rejections relying on Ye, applicant's arguments here appear to largely parallel the arguments made with respect to Nankai. Those arguments are similarly unpersuasive here as well. Applicant further urges that the ferricyanide of Ye is not included in the glucose standard, but rather is applied to the glucose sensor. However, this mediator is solvated into the standard solution upon addition of the solution to the sensor (col. 6, ll. 44-52). Hence the reducing substance of Ye eventually gets incorporated into the standard solution.

26. With respect to the 103 rejection of Ye in view of WO '705, applicant urges that Ye fails to disclose the claimed features of claim 6 because Ye relied on the addition of an organic solvent to the control solution resulting in a read/burn profile different from blood. This argument is not understood. Where do the claims exclude the addition of an organic solvent? As discussed in the previous office action, Ye discloses all the limitations of the claimed standard solution and Ye and WO '705 rendered obvious all the limitations of the rejected method claims. It is unclear how Ye's use of an organic solvent somehow reads free of the claimed invention. The examiner acknowledges that the discrimination in Ye differs from the discrimination of the

present invention. In particular, Ye seeks to reduce the burn current by utilizing substances that minimize the oxidation current during the burn period in contrast to the present invention. However, that distinction has not been made in the set forth method of claim 6.

27. With respect to the use of EP '234, applicant urges that EP '234 applies a voltage before the sample is supplied. This argument is irrelevant as the examiner is not relying on EP '234 as a teaching for the claimed pulse sequence. The combination of Ye and WO '705 already set forth the claimed pulse sequence. The examiner relied on EP '234 solely for its teaching of the use of a discrimination index to differentiate sample measurements from standard measurements. See paragraph 22 from the 11/30/2007 office action (reprinted above).

Conclusion

28. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAJ K. OLSEN whose telephone number is (571)272-1344. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam X. Nguyen can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kaj K Olsen/
Primary Examiner, Art Unit 1795
July 30, 2008